

Contract Modification Summaries

Exhibit 151

Part D RAC
ACLR
Claim Exhibits

Contract Modification Summaries

AQ1118
1672

Amend #	Effective Date	Deadline Extended	Contract No. GS-23F-0074W / Task Order No. HHSM-500-2011-00006G Nature or Modification(s)	Accord or Satisfaction Clause	Contracting Officer	Contract Specialist	COA/COB	ID
Contract No. GS-23F-0074W / Task Order No. HHSM-500-2011-00006G	01/13/11	Base Period Extension Eliminated at DVI Execution	Award with Original PWS; Contingency Fee 7.5%	N/A	Ms. Debra Stidham, Ms. Theresa Schultz, & Ms. Desiree Wheeler*	Ms. Jessica Sanders	Ms. Mamie Dorsey	A00352 A00423
Modification 000001	08/05/11	N/A	Payment Methodology Scale Revision	No	Ms. Debra Stidham, Ms. Theresa Schultz, & Ms. Desiree Wheeler*	Ms. Jessica Sanders	Mr. Frank Chartier	A00424 A00427
Modification 000002	01/12/12	01/31/12	Base Period Extension	No	Ms. Theresa Schultz	Ms. Jessica Sanders	Mr. Frank Chartier	A00428 A00429
Modification 000003	01/31/12	08/31/12	Base Period Extension, Special Study PY07 Excluded Provider Review Temporary 12% Fee Increase, Key Personnel Waiver Appeal Initiation, CO & COR Change, Express Special Study Deadline Execution	No	Ms. Theresa Schultz	Ms. Jessica Sanders	Mr. Frank Chartier	A00430 A00436
Modification 000004	04/06/12	09/30/12	Base Period Extension, Extend DVC/CMS Special Study Deadlines, ACLR FTP Development	No	Ms. Theresa Schultz	Ms. Jessica Sanders	Mr. Frank Chartier	A00437 A00441
Modification 000005	09/27/12	03/31/13	Base Period Extension, Eliminate Special Study Deadlines, CO & COR Change	No	Ms. Nicole Hoey	Mr. Justin Menefee	Ms. Sonja Brown	A00442 A00448
Modification 000006	02/06/13		Special Study PY08-PY11 Excluded Provider Review	No	Ms. Nicole Hoey	Mr. Justin Menefee	Ms. Sonja Brown	A00449 A00453
Modification 000007	04/01/13	09/30/13	Base Period Extension	No	Ms. Nicole Hoey	Mr. Justin Menefee	Ms. Sonja Brown	A00454 A00463
Modification 000008	07/15/13		Special Study PY09 Duplicate Payment Review 3 Contracts	No	Ms. Nicole Hoey	Mr. Justin Menefee	Ms. Sonja Brown	A00464 A00466
Modification 000009	09/30/13	10/31/13	Extend Period of Performance	No	Ms. Nicole Hoey	Mr. Justin Menefee	Ms. Sonja Brown	A00467 A00468
Modification 000010	10/31/13	11/30/13	Extend Period of Performance	No	Ms. Nicole Hoey	Mr. Justin Menefee	Ms. Sonja Brown	A00469 A00470
Modification 000011	11/19/13		PY08-PY11 Excluded Provider Review Temporary Fee Increase 16%	No	Ms. Nicole Hoey	Mr. Justin Menefee	Ms. Sonja Brown	A00471 A00472
Modification 000012	11/27/13	12/31/13	Extend Period of Performance	No	Ms. Nicole Hoey	Mr. Justin Menefee	Ms. Sonja Brown	A00473 A00474
Modification 000013	12/31/13	12/31/13	Incorporate New SOW, Eliminate 2 Option Years, PY08-PY11 Excluded Provider Review 28%, PY10-PY11 DEA Schedule Refill Review 16% if Issue Approval, Recoveries to \$10 Million 15% Fees, then 12%, PY10-PY12 Unauthorized Prescriber Review 12%	No Accord, Contractor expressly disagreed with Satisfaction Language, CO Agreement for ADR	Ms. Nicole Hoey	Mr. Justin Menefee	Ms. Sonja Brown	A00475 A00515

Part D RAC
ACLR
Claim Exhibits

Contract Modification Summaries

201119
2012

Contract No. GS-23F-0174W / Task Order No. HHSM-500-2011-00060								
Amend #	Effective Date	Deadline Extended	Nature or Modification(s)	Accord or Satisfaction Clause	Contracting Officer	Contract Specialist	COA/COR	IS
Modification 000014	03/28/14	05/28/14	Key Personnel Change	No	Ms. Nicole Hoey	Mr. Justin Menefee	Ms. Sonja Brown	A00516-A00518
Modification 000015	10/28/14	10/28/14	Administrative Modification	No	Ms. Nicole Hoey	Mr. Justin Menefee	Ms. Sonja Brown	A00519-A00521
Modification 000016	12/31/14	01/01/15	Awarded Option Year 2; Modified SOW for Rule 4159F	No	Ms. Nicole Hoey	Mr. Justin Menefee	Ms. Sonja Brown	A00522-A00563

May 6, 2013 Email

Exhibit 152

A02530

From: Christopher Mucke
 To: Brown, Sonja J. (CMS/CPI)
 Cc: Downs, Tanette N. (CMS/CPI)
 Subject: RE: Pharmacy Review
 Date: Monday, May 06, 2013 9:35:00 AM

Sonja,

I'm sorry I couldn't get back to you in more detail last week [family emergency] but I want to clear up what I believe may be some misunderstandings on what we did/did not do with respect to pharmacies. As I explained in our April 26th meeting with the RVC, we reviewed all new excluded pharmacies [22 during the 2008 - 2011 review period]. We could not, however, determine, with any reasonable amount of certainty, whether our efforts correctly identified the excluded party. Because of this, we had no excluded service providers with which to conduct our review and, as such, did not match any identifiers to the PDE data (there were no identifiers to match).

For my part, I thought that you were directing us to match excluded pharmacy identifiers to the PDE data despite the fact that we could not verify that the correct excluded provider had been properly identified. As I attempted to explain in my voice mail, I am uncomfortable with this (we did have a 100% error in the last review). If this is what you are requesting, we will of course comply but request that the OIG review and confirm each service provider (and concomitant identifier) as being the correct excluded party and that the exclusion has not been overridden by any letters similar to that done previously.

As to the rest, our frustration in the last audit was limited to not being made aware of the existence of the letters. While I still do not understand how the OIG could make those determinations (the facts of each case indicated an opposite result) we do recognize that the OIG, under law, is responsible for the determination of exclusionary status. We also recognize that the current modification requires us to review the pharmacies, which, as explained above, was done; I was just surprised that you were pushing the issue because the draft SOW indicated that you were no longer interested in so doing.

Please let me know how to proceed. Thank you, Chris.

Christopher Mucke | Managing Principal | ACLR, LLC
 38705 7 Mile Rd, Ste 460 | Livonia, Michigan 48152-3975 | ☎ (734) 744 - 4401 | ✉ (734) 744 - 4150 |
<mailto:cmucke@aclrllc.com>

The information contained in this message may be privileged and confidential and protected from disclosure. If you are not the intended recipient or an employee or agent responsible for delivering this message to the intended recipient, you are hereby notified that any review, distribution, copying of, or taking action in reliance on this communication is strictly prohibited. If you have received this communication in error, please notify the sender immediately by replying to the message and deleting it from your computer.

From: Brown, Sonja J. (CMS/CPI) [<mailto:sonja.brown@cms.hhs.gov>]
 Sent: Friday, May 03, 2013 5:39 PM
 To: Christopher Mucke
 Cc: Downs, Tanette N. (CMS/CPI)
 Subject: Pharmacy Review

Chris,

I received your voicemail in response to CMS' direction to include pharmacies in the 2008-2011 review. I understand your frustration with how the pharmacy reviews were handled for plan year 2007, however, as we've mentioned in previous conversations, CMS cannot override the OIG's decision. The only thing we're able to do is to provide enough documentation and/or evidence to support our findings and leave it up to the OIG for the final decision. With that said, CPI is still held accountable for ensuring that the RAC's review include identifying improper payments related to prescriptions prescribed by excluded providers as well as prescription drugs dispensed by excluded pharmacies.

In addition, you mentioned that you did not believe the review of pharmacies was in the parameters of the contract. It is our understanding that Modification 7 extends the timeframe to perform the activities outlined in Modification 6. When CMS implemented Modification 6 to include the review of 2008 through 2011 data, Section 14 stated the following

"The purpose of this modification to Task Order No. HHS/M-500-2011-00006G under GSA Contract No. GS-23F-00744 is to include the requirement for the review of 2008-11 POE data related to potential excluded pharmacies/prescribers"

I hope this clears up any questions that you may have. However, if you believe this requires a discussion with OAGM, we can set

EP2007

A02531

up a call with Jason and Nicole next week

Please contact us with any additional questions and/or concerns

Thanks,

Sonja J. Brown
Centers for Medicare and Medicaid Services
Center for Program Integrity
Division of Plan Oversight and Accountability
410-786-3571
Sonja.Brown@cms.hhs.gov

EP2008

Excerpts from the Deposition of Tanette Downs

Exhibit 153

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

-----x

ACLR, LLC

Plaintiff,

-vs-

Civil Action No. 15-767

THE UNITED STATES

(Judge Campbell-Smith)

Defendant.

-----x

Monday, November 20, 2017

Baltimore, Maryland

THE DEPOSITION OF TANETTE NICOLE BURDEN-DOWNS

The deposition of TANETTE NICOLE BURDEN-DOWNS was taken on Monday, November 20, 2017, commencing at 11:12 a.m., at the Department of Health and Human services, Office of General Counsel, 7500 Security Boulevard, Central Building, Baltimore, Maryland, before CHERYL NICHOLSON, CCR, CLR, Stenotype Reporter and Notary Public in and for the State of Maryland.

Tanette Nicole Burden-Downs
Case No. 15-767

ACLR, LLC v. THE UNITED STATES
November 20, 2017

1 second email on the first page, which is from
2 Teresa Dangerfield to Frank Chartier and then
3 cc's you, for PRIS interface system
4 requirements. And Teresa Dangerfield writes: I
5 updated the forms for your review. Let me know
6 if you and Tanette want to move forward with
7 ACLR's connectivity request.

8 Do you recall what that was about?

9 A. I don't.

10 Q. Then there's an email on -- the very
11 first email on Exhibit 74 from Frank Chartier to
12 you, and you want to focus on the second
13 paragraph, which said: Also, I contacted OAGM
14 regarding the SOW and received an interesting
15 forward sent from Gil Mucke. It stated that
16 they have no problem with any of the SOW
17 changes. I'm hoping ACLR isn't just being
18 cordial/amicable until they receive payment and
19 then walk away from the contract, but I find it
20 interesting that before I was here, they had a
21 mass of issues (most of the issues are still in
22 the SOW) but now Chris and Gil have no issues as

Tanette Nicole Burden-Downs
Case No. 15-767

ACLR, LLC v. THE UNITED STATES
November 20, 2017

1 written.

2 So do you recall what Frank was
3 talking about?

4 A. No.

5 Q. Did you do anything in response to
6 this email?

7 A. Yeah, I don't recall doing anything.
8 Again, I don't know why, if there were no
9 issues, it wasn't signed.

10 Q. If there were no issues, it should
11 have been signed, correct?

12 A. Exactly. So I don't -- yeah.

13 Q. Frank writes on there: I'm hoping
14 ACLR isn't just being cordial/amicable until
15 they receive payment and then walk away from the
16 contract.

17 Was there a concern by CMS that ACLR
18 would walk away from the Part D RAC contract?

19 A. I believe ACLR threatened on more than
20 one occasion that they would walk away.

21 Q. And tell me about when those instances
22 occurred.

Draft SOW Summary

Exhibit 154

Part D RAC

Draft SOW Summary

A04129

ACLR

Claim Exhibits

Contract No. G5-23F-0074W / Task Order No. HHSM-500-2011-00006G - SOW Revisions			
Revision	Draft SOW Submission	ACLR Response	CMS Feedback
1	12/09/11	12/14/11	01/04/12
2	04/19/12	04/20/12	09/13/12
3	03/21/13	03/22/13	N/A
4	12/31/13	12/31/13	Contract Execution
5	12/31/14	12/31/14	Contract Execution
6	01/08/15	SOW Modification Notification	

July 2, 2013 Email

Exhibit 155

From: Gil Mucke
To: Christopher Mucke
Subject: FW: Phone call comments
Date: Friday, July 05, 2013 9:16:38 AM
Attachments: Copy of 05 31 13 - ACLR Financials.xlsx
Copy of 03 13 13 Part D SOW - Proposed Audit Cycle (2).xlsx

From: Gil Mucke
Sent: Tue 7/2/2013 8:09 PM
To: Schultz, Theresa A. (CMS/OAGM) [Theresa.Schultz@cms.hhs.gov]
Subject: Phone call comments

Theresa,

Called and figured I should probably ask via email. Pam said I had a plan, not sure you were on the call yet, and I was unsure of her request... probably missed an opportunity of some type - sorry. Our discussion we had last week covered a few areas so I was not sure of her request. That said, you did make a statement that we had not formally requested ADR/Mediation and if you could pass me the info on the process, I would be appreciative.

As for Pam's request, the answer would create a contentious environment on the call which we are doing our best not to relive going forward and of course because Nicole asked us to be amiable. That said, the reason for our mediation request is to accomplish the following goals:

- Our FFP contract arrangement has exceeded any normal standard of minimum administrative burden over the last 2.5 years and that the administrative burden has to be reduced to a point that the contract is viable going forward. Program office has to have buy-in on this.
- The SOW has to be specific enough that all stakeholders are held accountable to the process timetables, that any changes to those timetables consider the cost impact to ACLR, and that the COTR and Contract Officer have control over any changes.
- That all parties have a complete understanding that the original contract provided ACLR full RAC execution (within the law) and the changes to date through the program office designing their processes have prevented ACLR from achieving resource potential and at minimum, sustainability costs. A cost burden that should not be placed on ACLR.

The first two are simple as they are in the realm of the way things should be. The last one is tough and unless there is some outcome on the \$1.8m delta now that there are captured funds on this contract, we are chasing this with contingency fees in hopes that are next discussion, if we make it, we catch up. Hope you made it this far and I forwarded the email I sent to Nicole (Cost and Delays) for help in your discussions.

Respectfully, Gil

From: Gil Mucke
Sent: Tue 6/18/2013 11:02 AM
To: Nicole.Hoey@cms.hhs.gov
Cc: Justin.Menefee@cms.hhs.gov
Subject: Info Requested

Nicole,

As discussed, financial cost statement is attached. Cost through first 1.5 years were high based on original awarded contract support which has been reduced though modifications and changes. Chris

has negotiated an office move which reduced office cost although infrastructure is average \$30-35k and employment cost minimum \$11k. To date, we have received \$223,813.26 in contingency fees. Our best guess for fees is \$300k for 2008-2009 and \$150k 2010-2011 and 12%.

Also attached a spreadsheet to show past, present and future audit cycle times. Includes following tabs:

2012 Mod 3-5 Audit Cycle Tab: Planned and actual 2007 Excluded Provider dates. Complete and ended a 14 month payment cycle. Of note, many preliminary process steps were complete prior to cycle.

2013 Mod 6-7 Audit Cycle: Displays planned cycle time based off of CMS timetable. We have modified/split the years based on recent news although we are not sure at what step the 2008-2009 cycle needs to be prior to sending notification letters to the providers for the 2010-2011 group.

2014 SOW Audit Cycle: Assumes process is approved prior to signature, RFI letters can be sent at SOW signing, and all steps are held to the schedule (no delays). Shows 12 months actual cycle although with increased accountability to process steps, 14 months is more realistic.

Hope this helps and as always, available for any questions.

Thanks for the assistance, Gil

August 21, 2013 Email

Exhibit 156

A02338

From: Christopher Mucke
To: Brown, Sonja J. (VCMS/CP1)
Subject: NAIRP - Schedule II, III, & IV Refill Errors
Date: Wednesday, August 21, 2013 4:09:02 PM
Attachments: NAIRP - Schedule Refill Errors .xlsx
 DEA Schedule Refill Errors - Summary of Amounts Owed by NDC.xlsx
Importance: High

Sonja,

Please find attached the New Audit Issue Review Package for Schedule II, III, & IV Refill Errors. As outlined in the document, we utilized the NDC database maintained by the FDA to generate our findings. As we discussed, I believe access to the CMS NDC database would yield more reliable results (the OIG report for 2009 resulted in twice the overpayments; their NDC source was First Databank) but we can proceed with this issue upon approval. I have also provided a summary of errors by drug code, which may provide additional insight. Please let me know if you have any questions. Thank you, Chris.

Christopher Mucke | Managing Principal | ACLR, LLC
 38705 7 Mile Rd, Ste 251 | Livonia, Michigan 48152-3975 | ☎ (734) 744 - 4401 | 📠 (734) 744 - 4150 | ✉
<mailto:cmucke@aclrsbs.com>

The information contained in this message may be privileged and confidential and protected from disclosure. If you are not the intended recipient or an employee or agent responsible for delivering this message to the intended recipient, you are hereby notified that any dissemination, distribution, copying or taking of action in reliance on this communication is strictly prohibited. If you have received this communication in error, please notify the sender immediately by replying to the message and deleting it from your computer.

August 29, 2013 Email

Exhibit 157

A01297

From: Christopher Mucke
To: Brown, Sonja J. [CMS/CPA]
Subject: NAIRP - Invalid Prescriber Identifiers
Date: Thursday, August 29, 2013 10:03:48 AM
Attachments: NAIRP - Invalid Prescriber Identifiers.pdf

Sonja,

I've attached the NAIRP for the invalid prescriber identifier issue. Please let me know if you have any questions or require additional assistance. Thank you, Chris.

Christopher Mucke | Managing Principal | ACLR, LLC
38705 7 Mile Rd, Ste 251 | Livonia, Michigan 48152-3975 | ☎ (734) 744 - 4401 | 📠 (734) 744 - 4150 |
<mailto:cmucke@aclrllc.com>

The information contained in this message may be privileged and confidential and protected from disclosure. If you are not the intended recipient or an employee or agent responsible for delivering this message to the intended recipient, you are hereby notified that any dissemination or distribution of, copying of, or taking action in reliance on this communication is strictly prohibited. If you have received this communication in error, please notify the sender immediately by replying to the message and deleting it from your computer.

**Excerpts from the Deposition of Christopher
Martin Mendez as Corporate Representative
for Livanta, LLC**

Exhibit 158

IN THE UNITED STATES COURT
OF FEDERAL CLAIMS

-----x

ACLR, LLC

Plaintiff,

-vs-

Civil Action No. 15-767

THE UNITED STATES

Defendant.

-----x

Monday, October 30, 2017

Reston, Virginia

THE DEPOSITION OF CHRISTOPHER MARTIN MENDEZ
As Corporate Representative for Livanta, LLC

30(b)(6)

Volume 1

Christopher Martin Mendez
Case No. 15-767

ACLR, LLC v. United States of America
October 30, 2017

1 Livanta did, what was the margin of error?

2 A. Where is that term, please?

3 Q. It's --

4 A. Oh, I see it right here. Okay.

5 Okay. Margin of error in this context
6 means sampling error. Sampling means we were
7 performing sampling and doing work based on a
8 sample. As I've explained, we were not tasked
9 to perform accuracy reviews in accordance with
10 Task 4, which was based on a sample. So this is
11 not relevant. It never happened.

12 Q. So there were never any accuracy
13 reviews performed by Livanta?

14 A. There were never any accuracy reviews
15 performed in accordance with Task 4. That
16 defined what an accuracy review is.

17 Q. Okay. Were there accuracy reviews
18 performed by Livanta under the Part D RAC?

19 A. There were no accuracy reviews that
20 were performed. We were asked at one point in
21 time to determine an accuracy rate based on the
22 validations that had been performed.

Christopher Martin Mendez
Case No. 15-767

ACLR, LLC v. United States of America
October 30, 2017

1 increases, you needed a number in the quantity
2 dispensed. But as I'm saying here, we could not
3 apply this analytical test on the 2011 and 2012
4 data because in 99 percent of the cases that
5 field, for some reason, was blank. That's all
6 it says.

7 Q. So in the PDE records themselves that
8 were generated by the plan sponsors, there was
9 no quantity dispensed?

10 A. That field was blank for some reason.

11 Q. In PDE records isn't there supposed to
12 be a number in the quantity dispensed field?

13 A. I would think so. But there wasn't in
14 this case. So it's possible -- well, I'm
15 speculating, okay. And I don't want to do that.

16 Q. Are you aware that state law requires
17 that new prescriptions be issued for any dosage
18 change?

19 A. That's correct. Which is why I'm
20 saying here they look like. They simply -- on
21 the data analytics you cannot make a
22 determination if they're legitimate dosage

Christopher Martin Mendez
Case No. 15-767

ACLR, LLC v. United States of America
October 30, 2017

1 increases without looking at the scripts,
2 because you need a new script if the dosage was
3 increased.

4 Q. Wouldn't it be an obligation to put a
5 dosage number in a PDE record? Is that a field
6 that's supposed to be included in the PDE
7 record, the dosage amount?

8 A. Not to my knowledge.

9 Q. What about the quantity?

10 A. I mean, we worked with the PDE records
11 as they were. We had no say in what fields were
12 there, what fields weren't, why some were
13 populated, why some were not. We had no -- it
14 was just, worked with the data.

15 Q. Do you know what a service reference
16 number is?

17 A. My recollection is that's a field in
18 the PDE record. The service reference number.
19 It could be -- and I believe it is. So let me
20 just say that I'm not 100 percent certain. It's
21 been a while. I think it's the ID that the
22 pharmacy signs for a prescription.

**December 2011- January 2012
Email Exchange**

Exhibit 159

A02911

From: Sanders, Jessica B. (CMS/OAGM)
 To: Christopher Mucke
 Cc: Wheeler, Desiree Y. (CMS/OAGM); Gil Mucke
 Subject: RE: RAC Medicare Part D RAC Draft SOW
 Date: Wednesday, January 04, 2012 11:15:17 AM
 Attachments: DPOA Response to ACLR - Final.docx
 Part D RAC Draft SOW V2 010612.docx

Good Morning,

Attached are the CMS Program Office's responses to ACLR's questions regarding the SOW revision for the RAC for Medicare Part D requirement submitted on December 9, 2011. Additionally, attached is the second revision to the SOW which addresses the questions/answers provided to the first revision.

Please feel free to contact me if you have any questions or concerns regarding this matter.

Thank you.

Jessica B. Sanders

Contract Specialist
 Office of Acquisition & Grants Management (OAGM)
 Centers for Medicare & Medicaid Services
 Mailing Address: 7500 Security Boulevard, Mail Stop B2-14-21, Baltimore MD 21244-1850
 Physical Address: 7111 Security Boulevard, 2nd Floor Cube B2-12-24 Baltimore, MD 21244-1850
 ☎ (410) 786-1076
 .. (410) 786-9088
 jessica.sanders@cms.hhs.gov

IMPORTANT: This e-mail, including all attachments, constitute Federal Government records and property that is intended only for the use of the individual or entity to which it is addressed. It also may contain information that is privileged, confidential or otherwise protected from disclosure under applicable law. If the reader of this e-mail transmission is not the intended recipient, you are hereby notified that any dissemination, distribution, copying or use of this e-mail or its contents is strictly prohibited. If you have received this e-mail in error, please notify the sender by responding to the e-mail and then delete the e-mail immediately.

From: Christopher Mucke [mailto:cmucke@aclrsbs.com]
 Sent: Wednesday, December 14, 2011 4:35 PM
 To: Sanders, Jessica B. (CMS/OAGM)
 Cc: Wheeler, Desiree Y. (CMS/OAGM); Gil Mucke
 Subject: RE: RAC Medicare Part D RAC Draft SOW

Jessica, we have reviewed the SOW and have questions and comments on the attached document. Due to some unknown or not clearly defined areas, we compared our review to the "Part D RAC BPM Updated models" emailed December 9, 2011 from the COTR for clarification. Since the updated model meeting is not taking place until the first week of January, we are hopeful that we can continue to work this SOW so that remaining questions may be resolved prior to the meeting. Thank you for following through on this and we look forward to the responses.

Christopher Mucke | Managing Principal | ACLR, LLC
 38705 7 Mile Rd, Ste 460 | Livonia, Michigan 48152-3975 | ☎ (734) 744 - 4401 | 📠 (734) 744 - 4150 |
 mailto:cmucke@aclrsbs.com

The information contained in this message may be privileged and confidential and protected from disclosure. If you are not the intended recipient or an employee or agent responsible for delivering this message to the intended recipient, you are hereby notified that any dissemination, distribution, copying or delaying action on this information is prohibited. If you have received this communication in error, please notify the sender immediately by replying to this message and deleting it from your computer.

From: Sanders, Jessica B. (CMS/OAGM) [mailto:Jessica.Sanders@cms.hhs.gov]
 Sent: Friday, December 09, 2011 11:04 AM
 To: Christopher Mucke
 Cc: Wheeler, Desiree Y. (CMS/OAGM)
 Subject: RAC Medicare Part D RAC Draft SOW

Good Morning,

As promised, attached is the draft Statement of Work (SOW) revision for the Recovery Audit Contract (RAC) for Medicare Part D

A02912

Please review and provide your questions/comments by COB Friday, December 16, 2011.

Thank you

Jessica B. Sanders

Contract Specialist
Office of Acquisition & Grants Management (OAGM)
Centers for Medicare & Medicaid Services
Mailing Address: 7500 Security Boulevard, Mail Stop B2-14-21, Baltimore MD 21244-1850
Physical Address: 7111 Security Boulevard 2nd Floor Cube B2-12-24, Baltimore MD 21244-1850
☎ (410) 786-1076
(410) 786-9088
jessica.sanders@cms.hhs.gov

IMPORTANT: This e-mail, including all attachments, constitute Federal Government records and property that is intended only for the use of the individual or entity to which it is addressed. It also may contain information that is privileged, confidential, or otherwise protected from disclosure under applicable law. If the reader of this e-mail transmission is not the intended recipient, you are hereby notified that any dissemination, distribution, copying or use of this e-mail or its contents is strictly prohibited. If you have received this e-mail in error, please notify the sender by responding to the e-mail and then delete the e-mail immediately.

12AR002

DPOA Response to ACLR's SOW Questions

1. Q: What is the process for taking "random samples" and how will it be applied?
A: This is in reference to the DVC randomly sampling the entire population of improper payments identified by the RAC. This will be for the DVC to determine in terms of the process for taking random samples. As to how it will be applied, for each IPRP received, the DVC will test a randomly selected sample of improper payments. They will test these for whether they concur with ACLR's determination of an improper payment. ACLR will be responsible for resolving any discrepancies with the DVC's review. The DVC will further explain this process during the January 3rd meeting.

2. Q: ACLR is requesting explanation of "specific criteria" to submit to CMS as improper payments and new audit issues.
A: Specific criteria related to ACLR's submissions to CMS within the audit scope can be defined two ways.

First, as it relates to improper payments, CMS will dictate to ACLR the specific items required to submit to CMS (and through an IPRP) when identifying an item as an improper payment. As CPI has only identified three audit issues to date, a more specific definition cannot be provided due to the lack of information related to any unidentified audit issue.

Second, as it relates to new audit issues, this dictates that CMS reserves the right to determine which specific criteria ACLR should provide as part of their task of identifying possible new audit issues. As mentioned above, once new audit issues are identified, CMS will determine the items required for submission to CMS when identifying an item as an improper payment.

3. Q: ACLR is requesting additional detail for review of duplicates.
A: CMS is fine with ACLR's initial methodology for determining duplicates (PDEs submitted for the same beneficiary, same date and same medication). However, after identifying the potential population, ACLR will need to perform additional procedures to determine whether all duplicates in the initially determined population were in fact duplicates. At a minimum, this will include sending a Request for Information (RFI) letter to the SO allowing them to provide support for what they feel to be erroneously identified improper payments. CMS does not want to restrict ACLR's professional judgment by dictating any other procedures aside from the RFI request. ACLR will need to review this documentation and make any necessary adjustments prior to submitting the final review package to PRIS.

The procedures above will be incorporated into ACLR's first review procedures, and will only become part of the 30 day appeal window if supporting documentation is submitted with the SO's appeal. ACLR should provide the SOs with a 30 calendar day time frame for submitting any supporting documentation. If the SO does not meet ACLR's due date, ACLR can proceed with calculating the improper payment and submitting the review package.

The RFI can be sent as an electronic notice to the SO. CMS will provide a template for ACLR's use.

4. Q: What is the format of the IPRP?
A: The IPRP should consist of 1 contract, one issue type and 1 audit year along with supporting documents PDE records; documents received from the SO and additional documents to support the improper payments.
The IPRP will also include the Improper Payment amount and the Contingency fee amount.

A02914

Until PRIS is operational – the interim process for IPRPs consist of

1. PDE records will be saved in CMS approved naming convention in a csv file format. The file will be uploaded to the HHS portal.
2. The IPRP will be entered or imported into the iPRIS application
3. The supporting documentation will be saved in CMS approved naming convention in a PDF file formation. The file will be uploaded to the HHS portal.

5. Q: ACLR is requesting additional information related to the New Issues Review Board.

A: Please reference the Standard Operating Procedures. In summary, the new audit issues can be identified and proposed by CMS, the DVC or ACLR as they are discovered.

The new audit issues review board is a group within DPOA that is currently prepared to review proposed newly submitted audit issues. The Board will meet as required by the frequency of issues to review. The decision to pursue a new audit issue will be a discussion involving multiple groups within CMS, the details of which may not be disclosed. This will occur internally prior to posting any final decision on the RAC website.

A New Audit Issue Review Package can be submitted in whatever format the submitting party feels appropriate based on their justification for the new audit issue.

6. Q: ACLR is requesting details related to the max limit of 5 new audit issues per year.

A: CMS has decided upon five new audit issues per year. This decision has multiple reasons as its basis. For one, CMS does not want to overburden the SOs by possibly implementing up to five audit issues per year. The limit is meant to minimize the amount of improper payments that would be repaid in one period of time. In addition, CMS does not want the quality of work for our contractors to suffer as result of being under too many time and work constraints. This maximum is meant to minimize that risk.

To clarify, the five per year limit is in reference to five approved issues per calendar year. As new audit issues are approved they can be implemented within an open audit year with a new SOW modifying any expectations from CMS.

7. Q: Why are terminated contracts being excluded?

A: DPOA's justification for removing terminated contracts is that there is no simple (or potentially feasible) way of collecting on improper payments. To avoid ACLR from performing work that will never result in collection, we are removing those contracts.

8. Q: How does CMS anticipate offset being implemented (these contracts are excluded from further RAC review)?

A: If a contract is currently going through the collection process (waiting on the 30 day appeal window or currently paying their offset), they will be excluded from being included in another review until this process is complete. A grouping of issues for one offset will not be an option as issues are audited one at a time.

CMS' intention is to recoup the improper payment from the SO through a lump offset.

9. Q: Does excluded from further review mean for a particular issue or all future issues?

A: In this circumstance, the SO is only excluded from the one particular audit issue, not all future issues. This answer applies to Comment 10 as well.

10. Q: (Comment 11) What are the requirements for validating the PDEs?

A02915

A: CMS anticipates that in most cases the PDE database should tie to the reconciliation database for all fields, within a few dollars (usually due to rounding). Any differences outside of this should be referred back to CMS.

11. Q: (Comment 13) What documentation should be compiled as it relates to beginning work on a new audit issue?

A: The RAC should compile any documentation necessary for the testing of the current audit issue. This will vary; however, the RAC should use the RFI as a means of obtaining necessary documentation from the SO.

12. Q: (Comment 14) ACLR wants explanation on the required discussion prior to beginning a new audit issue.

A: CMS feels it is necessary for ACLR to consult with CMS prior to beginning work on a new audit issue. To ensure that CMS and ACLR both have the same understanding of what might be required during the testing of a new audit issue, thorough discussions must occur. This is crucial for CMS to ensure that supportable findings will result from the audits. These discussions must occur prior to any work beginning, but most likely soon after a new audit issue has been determined.

Consultation/ discussion with CMS will in most cases result in additions to the SOW due to the nature of the Part D program. Not all audit issues can be audited and presented in the same fashion, so additions to the SOW will be done on a continuous basis (as new issues are identified).

13. Q: (Comment 15) What are the additional steps required (related to DIR)? When will these steps be completed and added to the SOW?

A: In this section of the SOW, when DPOA says "additional steps" this means that procedures ACLR intends to use for excluded providers and duplicates will not be sufficient for DIR. The basis for excluded providers and duplicates was to run various databases against each other; as explained in the draft SOW this would not be applicable for auditing DIR.

To answer the second question, CMS is not providing ACLR with an audit program, so exact *steps* will not be provided (or added to the SOW). However, as discussed in response 12 above, CMS feels it is necessary for ACLR to consult with us prior to deciding on their audit procedures. CMS wants to ensure that any over/ understatement in DIR are supportable.

14. Q: (Comment 16) What are the circumstances under which a site visit may be necessary?

A: Testing for DIR will require ACLR to review contracts, spreadsheets, etc. related to DIR. Often times SOs or their PBMs do not allow certain privileged information contained in their contracts to leave their work site. ACLR will need to work with these outside parties to coordinate where DIR information can be reviewed. If the SO or PBM does not allow for off-site review or electronic review, ACLR will need to visit these locations.

15. Q: (Comment 17) What is the rationale for requiring the DIR examination prior to the ID of improper payments arising from other approved audit issues? What is the time frame for DIR testing?

A: CMS is using this area to describe how the testing of DIR is different from the testing of other audit issues. In short, once the audit procedures for DIR have been agreed upon between CMS and ACLR, then the standard procedures can be applied (i.e. analyzing for over/ understatements in DIR – Path 1, and analyzing for potential fraudulent activities – Path 2). The exam of the currently identified audit issues can be completed as previously discussed.

16. Q: (Comment 18) ACLR is requesting clarification on the DVC's procedures.

A: The DVC will be testing items from ACLR's IPRP on a sample basis. Please see the response to Comment 1 above.

Following the DVC's review, they will either agree or disagree with ACLR's findings. Any disagreement between these two parties will need to be resolved by both parties collaborating. The DVC will validate the UFR records identified by ACLR. If there are discrepancies, these will be included in the dispute discussions between ACLR and the DVC.

17. Q: (Comment 19) ACRL wants to know whether there needs to be an additional letter sent for documentation requests and when this will be added to the SOW.

A: Any additional documentation required for ACLR's examination will be requested in advance of the Notification of Improper Payment Letter in the form of a Request for Information (RFI). Please see the response to comment 3 above. Discrepancies that involve the review of additional documentation should be resolved before the initial IPRP is submitted.

18. Q: (Comment 20) ACLR wants additional information related to the appeals process. Why wait until the appeals process is complete to collect payment? Why is the appeals process different from the A and B process considering that we are using a DVC?

A: The rationale for postponing collection of improper payments until the appeals process is exhausted has two justifications. First, if during the appeals process, changes are made to the IPRP, or higher authority within CMS agrees with the SO's appeal, this will negate any payment collected from that Plan. CMS does not want to collect payment up front from the plan, only to return it after the appeals process.

In addition, CMS feels using a DVC does not nullify the plan's right to appeal. Aside from the SO's right to appeal, the DVC serves as a check for ACLR's work, and the appeal allows the SO to support their position.

19. Q: (Comment 21) What are the time frames for the level 2 and level 3 appeals review?

A: DPOA is currently working on including additional detail to the appeals process. Please review the document when it is issued.

20. Q: (Comment 22) What is the process for adjusting monthly payments?

A: See response to comment 8, above.

21. Q: (Comment 23) How will ACLR be informed of amounts collected for the Plan? Through PRIS? When will this process be added to the SOW?

A: ACLR will be notified by an electronic notice from DPOA of the final amount collected from the SO. This will be included as part of the appeals process, which will be issued as an appendix to the SOW.

22. Q: (Comment 24) Does CMS anticipate another kick-off meeting upon contract modification?

A: CMS is adding this SOW as it relates to the current contract year. However, at the start of every new contract year, these basic requirements will need to be completed. This applies to the System Security Plan and the PWP as well.

23. Q: (Comment 26) What are CMS' expectations regarding the PWP?

A: To clarify and add detail to what is in the SOW:

A02917

Staffing – This should include which staff will be completing each portion of the examination. This should also include justification of how these staff members will be sufficient to complete all requirements, etc.

Review approach – This should address applicable audit issues and how ACLR plans to execute their examinations. ACLR should also include a timeline of how they plan to complete this.

Scheduling – This should answer the general timeline of when work will be completed.

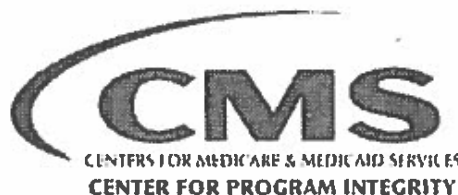
Risk and risk mitigation – We want ACLR to evaluate what risks they anticipate encountering during the examination. For example, not enough staff, insufficient documentation, etc.

24. Q: (Comment 27) Are the current key personnel ACLR has in place sufficient to meet CMS' expectations?
A: If the personnel currently in place meet CMS' requirements, there will not be a need to replace them; however, if they do not meet the requirements, they will need to be replaced. Currently, ACLR has proposed having key personnel share or fill multiple positions for which they are not qualified. Additionally, Key personnel are not eligible to fill concurrent positions.
25. Q: (Comment 28) When will the SOP be provided?
A: The SOP is currently in the review process. This will be issued upon it being completed.
26. Q: (Comment 29) Does CMS anticipate the website will contain the info provided on 12-9-2011?
A: Yes, the information provided during the 12/9/2011 meeting will be included on the RAC website.

**July 2, 2013 Medicare Part D RAC Data
Validation Center (DVC) Statement of Work**

Exhibit 160

DEPARTMENT OF HEALTH & HUMAN SERVICES
The Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244 – 1850



CENTER FOR PROGRAM INTEGRITY

Contract No. HHSM-500-2005-000131

Medicare Part D RAC Data Validation Contractor (DVC) Statement of Work

July 2, 2013

HHS02822

The Centers for Medicare & Medicaid Services
 RAC Data Validation Contractor SOW – Division of Plan Oversight and Accountability

Table of Contents

1.0	Introduction and Background	1 - 3
1.1	Commonly Used Terms and Acronyms	
1.2	Other Resources and Information	
1.3	DVC Introduction and Scope	
1.3.1	DVC Scope	
2.0	DVC Review Activities	3 - 6
2.1	New Issue Review	
2.1.1	New Issue Review Reporting and Tracking	
2.2	Accuracy and Improper Payment Review	
2.2.1	Accuracy/Improper Payment Review Reporting and Tracking	
2.3	Validation of RAC Audit Findings	
2.3.1	DVC/RAC Dispute Resolution	
3.0	Special Studies	6
4.0	DVC Requirements/ Tasks to be Performed	6 - 13
4.1	Basic Requirements	
4.2	System Requirements	
5.0	Key Personnel/Other Personnel	13 - 16
6.0	Quality Assurance	16 - 17
6.1	DVC Oversight	
6.2	Cooperation/ Coordination	
6.3	Quality	
6.4	Standard Operating Procedures	
6.5	CMS System	
7.0	Transitions	17
	Appendix A: Dispute Form for New Issue and Accuracy	18
	Appendix B: Items to be furnished and deliverable schedule	19
	Appendix C: CMS Contacts	20

The Centers for Medicare & Medicaid Services
 RAC Data Validation Contractor SOW – Division of Plan Oversight and Accountability

1.0 Introduction and Background

Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (P.L. 108-173) was signed into law on December 8, 2003. The MMA established a new voluntary outpatient prescription drug benefit under Part D of Title XVIII of the Social Security Act (the Act). The prescription drug benefit, referred to as Medicare Part D, as well as an employer subsidy for qualified retiree health plans, began on January 1, 2006. Coverage for the drug benefit will be provided by private prescription drug plans (PDPs) that offer drug-only coverage or through Medicare Advantage (MA) plans that offer both prescription drug and health care coverage (known as MA-PD plans). These plans must offer a standard drug benefit, but will have the flexibility to vary the drug benefit within certain parameters. The Centers for Medicare & Medicaid Services (CMS) has identified 26 MA Regions and 34 PDP Regions, not including territories, each of which is its own PDP region.

The Recovery Audit Contractor (RAC) Program, which is designed to ensure proper payments to Sponsoring Organizations (SOs) and providers, was initiated through demonstration programs mandated by the Medicare Modernization Act of 2003. The success of the initial pilot program for Medicare Parts A and B included the return of millions of dollars in overpayments to the Medicare Trust Fund. Based on that success, the Medicare Parts A and B RAC Program was permanently established on a national level through the Tax Relief and Healthcare Act of 2006.

Under the 2010 Patient Protection and Affordable Care Act (ACA) legislation enacted in March 2010, CMS is required to expand the RAC Program to the Medicare Part C (Medicare Advantage) and Part D (Prescription Drug Benefit) programs. Section 6411(b) of the ACA provides CMS with general authority to enter into contracts to conduct RAC audits in Medicare Part D. Under the Medicare Integrity Program (MIP), RACs are to identify underpayments and overpayments and recoup any overpayments made associated with the Medicare program. The Part D RAC is dedicated to identifying past improper payments in reconciled Medicare PDE claims and providing information to CMS to help prevent future improper payments.

To measure the accuracy rate of the Part D RAC, CMS contracts with a Data Validation Contractor (DVC). The DVC takes random samples of the improper payments identified by the RAC to determine if they are accurate. The DVC also review and approve/disapprove improper payment referrals, receive and review New Audit Issues the RAC wants to pursue for improper payments, and provide recommendations to the New Issues Review Board (NIRB).

1.1 Commonly Used Terms and Acronyms

For purposes of this Statement of Work (SOW), the following list addresses some of the commonly used terms within the Part D RAC Program.

- “Appeals Contractor” (Independent Review Entity) handles the first level of appeals from MAOs challenging RAC findings.
- “Audit Scope” is a list of audit issues the RAC is required to review during a given year.
- The “Center for Program Integrity” (CMS/CPI) serves as CMS' focal point for all national and state-wide program integrity, fraud and abuse issues in the Medicare and Medicaid programs, and the Children's Health Insurance Program (CHIP). Specifically, the Division of Plan Oversight and Accountability (DPOA) is the division within the CMS/CPI Medicare Integrity Group responsible for ensuring program integrity for Medicare Parts C and D, and oversees Medicare Parts C and D RAC.

The Centers for Medicare & Medicaid Services
 RAC Data Validation Contractor SOW – Division of Plan Oversight and Accountability

- The “Data Validation Contractor” (DVC) measures the accuracy rate of the RAC. The DVC reviews 100% or takes random samples of the improper payments identified by the RAC to determine if they are accurate and will review and approve/disapprove improper payment referrals, receive and review new audit issues the RAC wants to pursue for improper payments, and provide recommendations to the New Issues Review Board (NIRB).
- “Improper Payment Review Package” (IPRP) is an improper payment file and the supporting documentation for a particular audit issue by contract and year.
- “New Audit Issue Review Package” (NAIRP) is the package of proposed audit issues for a specified contract year, a new audit issue, an estimate of improper payment amount and the audit methodology.
- The “New Issues Review Board” (NIRB) is the planned CMS/CPI group that identifies, reviews, and approves Part D RAC audit issues.
- The “Payment Recovery Information System” (PRIS) houses referrals made to CMS/CPI after improper payments are identified. The RAC and DVC review the claims and their accompanying medical records and charges, either confirm or reject claims, and update the records with an approval or rejection to request money from the provider.
- The “Recovery Audit Contractor” (RAC) is responsible for reducing Medicare improper payments through the efficient detection and collection of overpayments, the identification of underpayments, and assists with the implementation of actions that will prevent future improper payments. Originally implemented for FFS Medicare, the ACA (Section 6411(b)) expands the original RAC Program to Medicare Parts C and D. RACs are paid for identified improper payments on a contingency fee basis.
- “Plan Sponsors are private organizations that contract with CMS to administer Medicare Parts C and/or D benefits and may offer several different types of Medicare Part C and/or Part D plans. Plan Sponsors include, but are not limited to, Medicare Advantage Organizations (MAOs), Medicare Advantage – Prescription Drug Plans (MA-PDPs), Prescription Drug Plans (PDPs).

1.2 Other Resources and Information

To gain additional knowledge potential bidders may research the following documents:

- The Debt Collection Improvement Act of 1996
- The Federal Claims Collection Act, as amended and related regulations found in 42 CFR,
- CMS Financial Report
http://www.cms.gov/CFORreport/Downloads/2009_CMS_Financial_Report.pdf
- The Medicare Prescription Drug Benefit Manual:
<http://www.cms.gov/Manuals/10M/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS050485&intNumPerPage=10>
- Part D Claims Data:
http://www.cms.gov/PrescriptionDrugCovGenIn/08_PartDData.asp#TopOfPage
- Part D Program Analysis:
http://www.cms.gov/PrescriptionDrugCovGenIn/09_ProgramReports.asp#TopOfPage
- Part D Regulations:
<http://www.cms.gov/PrescriptionDrugCovGenIn/PDR/list.asp#TopOfPage>
- Plan Communication Guide:
http://www.cms.gov/MAPDHelpDesk/02_Plan_Communications_User_Guide.asp
- Part D Reporting Requirements:
http://www.cms.gov/PrescriptionDrugCovContra/08_RxContracting_ReportingOversight.asp

The Centers for Medicare & Medicaid Services
 RAC Data Validation Contractor SOW – Division of Plan Oversight and Accountability

1.3 DVC Introduction and Scope

1.3.1 DVC SCOPE

The primary purpose of the RAC Data Validation Contractor (DVC) is to review RAC claim determinations on Medicare claims that were paid under Part D of title XVIII of the Social Security Act, and to ensure that the RAC only identify and attempt to recover claims resulting in an overpayment to the plan sponsors.

This SOW includes the following tasks which are defined in detail in subsequent sections of this contract:

- Reviewing new issues the RAC wants to pursue for improper payments where Part D plans have not been notified of an improper payment. The RVC will submit reports to CMS on their findings.
- Reviewing claims on which the RAC has made overpayment determinations. The RVC will also validate files used by the RAC to create overpayment notification letters (demand letters). The RVC will submit reports to CMS on their findings.
- Meeting and communicating with CMS and the RAC about their review findings, as well as developing public relations material upon CMS' request.

For the purposes of this SOW, CMS is not concerned with a RAC missing a potential overpayment (i.e., a RAC failing to identify an overpayment), only that a RAC may be inappropriately identifying an overpayment.

2.0 DVC Review Activities

2.1 New Issue Review

The DVC shall review the new issues that the RAC wishes to pursue for potential improper payments. Each proposed new issue will be reviewed based on the method identified by the RAC, either automated or complex review. Automated review occurs when determination is performed at the system level without a human review of the pertinent documents. In situations where there is high probability (but not certainty) that an improper payment was made outside the scope of automated reviews, complex review would be necessary (i.e. for DIR validation).

The DVC shall review each submitted claim, claim selection criteria, associated documentation (for complex reviews only), improper payment finding, reviewer rational, and denial type and subtype.

The DVC shall document the following findings for each claim in the study:

- for automated reviews only: whether the criteria for automated review was met (or whether the RAC should have performed complex review instead)
- whether the DVC agrees or disagrees with the RAC's claim of improper payment determination (full overpayment, partial overpayment, underpayment, etc.)
- for each disagreement: indicate the correct determination. At CMS' discretion the DVC may be required to recalculate recoupment amounts.
- whether the DVC agrees or disagrees with the RAC's error type (no documentation, insufficient documentation, or other) and subtype (to be provided by CMS) for the claim determination
 - for each disagreement, indicate the correct denial type and subtype

The Centers for Medicare & Medicaid Services
 RAC Data Validation Contractor SOW – Division of Plan Oversight and Accountability

2.1.1 NEW ISSUE REVIEW REPORTING AND TRACKING

The DVC shall submit to CMS one report per new issue. The DVC shall also provide a brief explanation (one to two sentences) for each claim reviewed communicating the reason for the DVC's finding. The DVC shall review previously submitted new issues and provide clarification and discussion upon CMS request.

The DVC shall provide a comparison and contrast (C/C) report for similar (i.e. edit parameters, rationale, provider type) or same new issues proposed by different RACs if CMS implements multiple RACs to handle Part D. The C/C report shall include a checklist including which findings each new issue proposal do or do not contain. This comparison and contrast is deliverable to CMS with the DVC new issue report under review.

The DVC shall track and report identified policy vulnerability issues during new issue review. The vulnerability report shall include recommended corrective actions the agency should undertake. This vulnerability report is a deliverable to CMS along with the DVC new issue report under review. At CMS' discretion, a standardized format for the report and/or tracking may be required. If a standardized format is required, CMS will provide the format.

New Issues Reviews can be accomplished as part of special studies as requested by CMS. When using this approach to accomplishing New Issues Reviews, the DVC shall determine the appropriate protocols to accomplish the work, e.g., analysis plan and audit plan, discuss the overall approach with CMS, and communicate the findings in a format appropriate to the type of the review, in accordance with a timeframe and format that is mutually agreeable by CMS and the DVC.

The report shall be delivered by the 25th calendar day, following the DVC's receipt of the claims, and will be in a format determined by CMS. The report shall be uploaded in PRIS or delivered to CMS.

2.2 Accuracy and Improper Payment Review

The DVC shall measure the accuracy rate for the RAC by reviewing a randomly selected sample of claims or 100% of the claims that the RAC has reviewed. CMS will provide Improper Payment Review Packages (IPRP) to the DVC which includes one audit issue, one plan, and 1 audit year. The RAC will add the packages to PRIS; the IPRP will be made available to the DVC for validation. The accuracy review begins once the DVC receives claim detail information from PRIS or otherwise noted by CMS. CMS will determine whether the RAC's accuracy shall be determined by sampling or as a 100% review. This decision will be evaluated separately for each new audit issue.

The DVC shall review each submitted improper payment review package and randomly select a sample of claims from each package to review for accuracy. The DVC shall also review associated documentation, edit parameters, improper payment finding, reviewer rationale, communication to provider, error type and subtype. The DVC will also review the letter sent to the provider communicating the improper payment finding and will develop a standardized checklist to assist in this review unless otherwise directed by CMS.

The DVC shall document the following findings for each claim in the study:

- for automated reviews only: whether the criteria for automated review was met (or whether the RAC should have performed complex review instead)
- whether the DVC agrees or disagrees with the RAC's claim of improper payment determination (full overpayment, partial overpayment, underpayment, etc)

The Centers for Medicare & Medicaid Services
 RAC Data Validation Contractor SOW – Division of Plan Oversight and Accountability

- for each disagreement: indicate the correct determination At CMS' discretion the DVC may be requested to recalculate recoupment amount
- whether the DVC agrees or disagrees with the RAC's error type (no documentation, insufficient documentation, or other) and subtype (to be provided by CMS) for the claim determination
 - for each disagree, indicate the correct denial type and subtype
- whether the DVC believes the language used by the RAC to communicate the improper payment to the provider was clear and accurate based on current CMS guidelines.
- The DVC shall agree or disagree with the following calculations
 - Improper Payment Amount
 - RAC Contingency Fee
 - Medicare Trust Fund Amount

Accuracy Reviews can be accomplished as part of special studies as requested by CMS. When using this approach to accomplishing Accuracy Reviews, the DVC shall determine the appropriate protocols to accomplish the work, e.g., analysis plan and audit plan, discuss the overall approach with CMS, and communicate the findings in a format appropriate to the subject of the review, in accordance with a timeframe and format that is mutually agreeable by CMS and the DVC

2.2.1 ACCURACY/IMPROPER PAYMENT REVIEW REPORTING AND TRACKING

The DVC shall submit to CMS via PRIS unless otherwise determined by CMS one Validation Findings report for each IPRP. The Validation Findings report shall describe the claim accuracy rates as well as a brief explanation (one to two sentences) for each improper payment reviewed communicating the reason for the DVC's finding. The report shall also include a narrative section with information about patterns of inappropriate denials that can be seen from the data. The report shall be delivered by the 45th day after the DVC's receipt of the claims. The report shall follow the name filing conventions assigned by CMS and uploading in PRIS or delivered to CMS via encrypted tools

Annually, the DVC shall write a cumulative report of the accuracy rate study. The report shall include the overall accuracy rates for the RAC, and a narrative section with information about patterns of inappropriate denials that can be seen from the data as well as recommendations to CMS regarding any needed policy(s) based on trends identified during review. The report shall also include corrective actions the agency should undertake when the DVC has identified a consistent pattern during accuracy reviews. The report shall be no more than (10) pages. The annual report shall be written in a format determined by CMS. CMS will specify the sampling period for the annual report. The report is due 60 days after the end of the fiscal year. A draft report is due to CMS 30 days after the fiscal year ends and a final report is due 30 days after the draft.

2.3 Validation of RAC Audit Findings

The DVC shall perform a review of the IPRP and to submit an IPRP validation finding to CMS. The DVC will follow the same review process as the RAC. The DVC will also validate the UFR records, the improper payment amount, and the contingency fee. The DVC will have 45 calendar days to complete its review process.

The RAC must agree or disagree with the validation findings submitted by the DVC. Concurred validation findings will continue through the RAC process.

The Centers for Medicare & Medicaid Services
 RAC Data Validation Contractor SOW – Division of Plan Oversight and Accountability

2.3.1 DVC/RAC DISPUTE RESOLUTION

When the RAC disagrees with the DVC new issue or accuracy determination, the dispute process shall follow with the dispute form (DF) or by a dispute indicator in PRIS. The DVC shall review the DF and submit a response to CMS within seven (7) days (Appendix A). The process will be subject to change at CMS' request. The dispute process will involve no more than five improper payment type accuracy reviews or new issues per RAC per month. Issues may consist of multiple claims with the same denial reason completed by automated review.

For RAC findings the DVC disagrees with, the DVC must provide a rejection reason and explanatory comments, including their recovery calculations.

The RAC is required to review all disagreements identified by the DVC and either accept or reject the DVC's validation findings. When the RAC agrees with a rejected IPRP Validation finding, the file is considered validated; all associated findings will be removed from the Unavailable for Review (UFR) file. When the RAC disagrees with the DVC, they must show support for their findings and offer assistance in understanding the process behind decisions to exclude these disputed findings. The RAC should submit this new package with updated data.

The DVC must collaborate with the RAC to attempt resolution of any dispute. Disputes will be entered and tracked through CMS systems. The DVC and RAC should attempt to resolve any disputes within 7 calendar days. If the DVC and RAC cannot come to a resolution, CMS shall make the final decision, which cannot be reviewed or contested by either the RAC or DVC. CMS does not need any statutory or regulatory reference to deny a RAC finding. CMS also has the right to establish minimums and thresholds that RAC findings must meet to be considered for recoupment. The RAC shall submit a new package with the final updated, CMS approved, audit findings.

3.0 Special Studies

The DVC shall review additional claims for special studies at CMS' request. For each special study, the DVC shall submit a report to CMS including, at a minimum, claim and dollar accuracy rates, a narrative section with information about patterns of inappropriate denials that can be seen from the data, as well as a brief explanation (one to two sentences) for each claim reviewed communicating the reason for the DVC's finding. The special study report shall also include recommendations and corrective actions for any policy(s) during the review. CMS has the discretion to request the DVC to recalculate recoupment amounts. Exact parameters for each special study will be determined by CMS prior to assignment.

The volume, frequency and extent of Special Studies shall be assigned and scheduled by CMS in consideration of the DVC resource constraints and the extent of concurrent New Issues Reviews and Accuracy Reviews. If at any time, third party databases that require additional funding are required to accomplish a study, the DVC shall bring the matter to the attention of CMS for a funding approval decision.

The Centers for Medicare & Medicaid Services
 RAC Data Validation Contractor SOW – Division of Plan Oversight and Accountability

4.0 DVC Requirements/Tasks to be Performed

4.1 Basic Requirements

Independently, and not as an agent of the Government, the DVC shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the requirements of this Statement of Work (SOW).

CMS will provide minimum administrative support which may include help communicating with Medicare contractors, policy interpretations, and other support deemed necessary by CMS to allow the DVC to perform its tasks efficiently. CMS will support changes it determines are necessary but cannot guarantee timeframes or constants. In changing systems to support greater efficiencies for CMS, the end product could result in an administrative task being placed on the DVC that was not previously. These administrative tasks will not extend from the tasks in this contract and will be applicable to the review of identification and recovery of the overpayment/underpayment. CMS can periodically conduct onsite visits to audit the DVC review functions and business practices.

Kick-off Meeting

The DVC shall work with the Contracting Officers Representative (COR) to determine a mutually agreeable time to conduct the Kickoff meeting. This meeting shall be held no later than 14 calendar days after the contract is awarded. The kickoff meeting shall include, at a minimum, the following information:

- Introduction of key personnel
- Discussion of the draft Project Work Plan and how work will be completed in order to meet deadlines
- List of all deliverables

Within 5 business days from the kick-off meeting, the DVC is required to electronically submit meeting minutes.

System Security Plan

The DVC shall ensure security of sensitive information as well as provide and implement a written security plan covering all aspects of this SOW. The Contractor shall maintain oversight of the physical location of the protected medical information and other proprietary information. The Contractor shall store and dispose of the records/documents/files containing protected medical information and other proprietary information in accordance with CMS guidelines, and as instructed by the COR.

Specifically, the DVC shall include a draft System Security Plan (SSP) using the current template available at the CMS Information Security "Virtual Handbook" Web site at: <http://www.cms.gov/InformationSecurity>. The details contained in the DVC's draft SSP shall be commensurate with the size and complexity of the other requirements of the SOW based on the System Categorization determined elsewhere in this document. The System Security Plan shall be submitted no later than 14 calendar days after contract award. The DVC shall be required to update and resubmit its SSP to CMS every three years (at a minimum) following award or when a major modification has been made to its internal system, as defined by the CMS Chief Information Security Officer (CISO).

The Centers for Medicare & Medicaid Services
 RAC Data Validation Contractor SOW – Division of Plan Oversight and Accountability

Project Work Plan

The DVC is required to submit a draft Project Work Plan (PWP) within 14 calendar days after the contract is awarded. The PWP is a description of how the DVC plans to accomplish the requirements of the SOW. Specifically, the PWP should include

- The DVC's review approach, staffing, scheduling, etc.
- All contact information for the DVC's staff
- Anticipated risk and risk mitigation

This document is subject to CMS review and acceptance. Upon CMS review, the DVC will submit a finalized PWP electronically. All PWPs shall be modified and updated continuously after the initial submission to reflect any major changes in the project. When changes are identified, a revised PWP should be submitted for review within 10 days of identifying the change. If no revisions are received, the resubmitted PWP should be considered final.

Quality Assurance Plan

The DVC shall develop a quality assurance (QA) plan to be approved by the COR. The plan shall include, at a minimum, a review of 10% of all claims reviewed, as well as a second level of review if the first-level reviewer disagrees with a RAC determination. The plan shall also include a process for when the second-level reviewer disagrees with the first-level reviewer.

If required, the DVC shall spend up to two hours per week at CMS discretion on activities aimed at ensuring the consistency of claim reviews between CMS and its claim review entities. The Program Director (PD) shall provide oversight of all issues under review included but not limited to new issue, accuracy, and special studies for quality assurance. The DVC shall electronically image reviewer's notes and any other documentation used to make an error determination. The RVC shall store these cases in such a way that they can be accessed immediately upon request. The DVC shall shred any case that has been successfully imaged. The DVC shall retain the findings for each claim indefinitely.

Monthly Progress Reports

The DVC shall submit Monthly Progress Reports to the COR and by the 10th of each month for the previous months' effort. The COR and the DVC shall agree upon the content and format of the Monthly Progress Report as this may change periodically. At a minimum, the monthly progress report should include:

- Number of new issue claims reviewed and agreement rate
- Number of accuracy claims reviewed and agreement rate
- Number of special study claims reviewed and a summary of study
- Number of identified vulnerability issues and a summary each issue
- Cumulative number of new issue claims reviewed incurred to date
- Cumulative number of accuracy claims reviewed incurred to date
- Cumulative number of special study claims reviewed incurred to date
- Complications completing any task
- Communication with RACs
- Communication with PRIS Contractor
- Action Items
- Problems Encountered
- Major Findings identified from new issue review and RAC monthly calls

8

HHS02831

The Centers for Medicare & Medicaid Services
 RAC Data Validation Contractor SOW – Division of Plan Oversight and Accountability

DVC Operations Manual

The DVC shall develop and maintain an approved DVC Operations Manual. The draft manual shall be submitted to the COR no later than 30 days after the initial contract award and at least quarterly thereafter. If no comments are received from the COR within 30 days of submission of a draft manual change, the DVC shall submit the final within 10 days after the COR comment period ends. The DVC Manual is a living document and may be updated without contract modification. The contractor shall provide written comments to the COR on changes, updates or corrections to the manual on a continual basis so that it will be kept current to accommodate workload and other changes in the DVC processes as necessary. Changes identified in revisions to the review manual are to be acted upon only if they fall within the general scope of the contract. The DVC manual documents the various processes that the DVC follows in its daily operations, including the process for obtaining, processing and reviewing medical records and claims, reporting procedures, and other processes and business rules as necessary.

Vulnerability Tracking

The DVC shall track and communicate vulnerabilities to CMS via a Vulnerability Tracking report. Vulnerabilities are identified in the following categories and tracked on an excel spreadsheet.

1. *Procedure Process*: Vulnerabilities that may affect current procedures or processes
2. *Regulatory*: Vulnerabilities that may affect current regulations
3. *Statutory*: Vulnerabilities that may affect current statutes
4. *Security*: Vulnerabilities that may be a threat or weakness to CMS systems or data

The Vulnerability Tracking report shall be submitted to CMS monthly via QuickR or email to COR and discussed during bi-weekly conference calls.

PRIS/RVC Integration

Once the DVC has established connections with CMS and the RAC over the secure CMS Net (formerly Medicare Data Communications Network (MDCN) and Multiprotocol Label Switching (MPLS) connectivity), the DVC shall integrate with the PRIS system within 60 days. The DVC/PRIS integration includes testing mock packages to ensure that the DVC can successfully pick up, process, move through the system and return back to CMS all packages.

Following DVC/PRIS integration, the DVC shall conduct training to appropriate staff (DVC/CMS) for utilization of the DVC system. The DVC shall use PRIS for all communication with regard to the three review types (new issue, accuracy, and special studies) unless otherwise noted by CMS. All communication in PRIS shall respond in the next 24 hours or the next business day.

CMS may need to access the DVC system. At a minimum the DVC shall provide the "read-only" accessibility for CMS upon request.

Conference Calls

CMS and the DVC shall meet bi-weekly via conference call for status updates and to discuss any process issues or vulnerabilities. CMS and the DVC shall have additional conference calls with the RACs as necessary to discuss the validation study. At the request of CMS, the DVC team shall consult with CMS Division of Plan Oversight and Accountability (DPOA) staff for any issues (policy, etc.) related to RAC review. The meeting schedule shall be flexible and can change as needed.

The Centers for Medicare & Medicaid Services
 RAC Data Validation Contractor SOW – Division of Plan Oversight and Accountability

The DVC shall provide phone lines for all scheduled bi-weekly calls. Beyond the initial kickoff and planning calls, the DVC shall facilitate each call, record the meeting minutes, and distribute meeting minutes after the call.

The DVC shall participate in monthly user group calls with DPOA and the MEDIC. The user group call will be used to identify trends, system issues, best practices, and upcoming events.

Quarterly Meetings

CMS and the DVC shall meet in person quarterly for project status updates and to discuss current and new audit issues, RAC program vulnerabilities, etc. Quarterly meetings will be coordinated between CMS and the DVC for an agreeable date, time and location. DVC key personnel are required to attend.

The DVC is required to electronically submit meeting minutes including any action items within 5 business days from the meeting.

4.2 System Requirements

The DVC shall possess appropriate hardware, software, and telecommunications equipment to undertake this SOW. Following award of the contract, the DVC shall establish connections with CMS and the RAC over the secure CMS Net (formerly Medicare Data Communications Network (MDCN)) and Multiprotocol Label Switching (MPLS) connectivity and site to site VPN. This connectivity will be used to access any information systems CMS develops for the Part C and Part D recovery auditing program. This connectivity shall also be used for sending Protected Health Information (PHI), and for communicating analysis findings and new issues electronically to CMS. When utilizing the public internet for communications that include PHI or other sensitive data, SecureZip or other FIPs-approved product may also be used by the RVC. Exrypted CDs and external hard drives are also permitted as communication mechanisms when either sending data among the parties by Federal Express or some other form of traceable mail and when making hand-deliveries of larger or special data files.

The DVC shall include this requirement in any subcontract awarded under this prime contract. If this SOW requires the DVC to (1) process, (2) store, (3) facilitate transport of, or (4) host/maintain Federal information, pursuant to Federal, DHHS, and CMS Information Security Program Policies the following requirements apply:

System Security Level

In the performance of this SOW, the DVC shall develop appropriate security controls for CMS security requirements (located on the CMS Information Security "Virtual Handbook" Web site at: <http://www.cms.gov/InformationSecurity>) in accordance with the below-listed parameters:

- a. Information Type (as defined on the CMS Information Security "Virtual Handbook" Web site at: <http://www.cms.gov/InformationSecurity>).
- b. Systems Security Level (Low, Moderate, or High as defined on the CMS Information Security "Virtual Handbook" Web site at: <http://www.cms.gov/InformationSecurity>).
- c. E-Authentication level (Level 1, 2, 3, 4, or N/A as applicable by NIST 800-53 controls 1A-2 and 1A-8 and as defined on the CMS Information Security "Virtual Handbook" Web site at: <http://www.cms.gov/InformationSecurity>).

The Centers for Medicare & Medicaid Services
 RAC Data Validation Contractor SOW – Division of Plan Oversight and Accountability

The DVC must coordinate with CMS to develop and/or clarify the above listed criteria within 30 days of contract award or when a major modification has been made to its internal system, as defined by the CMS Chief Information Security Officer (CISO)

Security Services

The DVC shall provide security services in support of CMS, which shall include coordination among the CMS CISO, business owners, and other stakeholders. The sites and related infrastructure services shall have policies and procedures and implement controls or plans that fulfill the CMS Information Security Policy requirements, including all applicable CMS standards and procedures. The collection of CMS policies, procedures, standards, and guidelines are located on the CMS Information Security “Virtual Handbook” Web site at: <http://www.cms.gov/InformationSecurity>

Tracking and Correcting Security Deficiencies

The DVC shall track and correct any applicable security deficiencies, conditions, weaknesses, findings, and gaps identified by audits, reviews, Security Assessments, and tests, including those identified in Chief Financial Officer (CFO) Audits, FISMA Audits, Statement on Auditing Standards (SAS) 70 reviews, MMA Section 912 evaluations and tests, Inspector General Audits, A-123 audits, other applicable reviews and audits, and CMS Security Operations Center (SOC) continuous monitoring activities such as, but not limited to, vulnerability and compliance scanning of all the CMS information systems, in a timely manner.

Incident Response

A security incident is a violation, or an imminent threat of a violation, of an explicit or implied security policy, acceptable use policies, or standard security practices. While certain adverse events, (e.g., floods, fires, electrical outages, and excessive heat) can cause system crashes, they are not considered computer-security incidents. A security incident becomes a breach when the incident involves the suspected or actual loss of personally identifiable information. CMS information and information system security related incidents should be reported using the Computer Security Incident Report (CSIR) form. Incidents that concern PII should be reported using the CSIR form set forth in the CMS Incident Handling procedures available at the CMS Information Security “Virtual Handbook” Web site at: <http://www.cms.gov/InformationSecurity>

Information Security Awareness Training

CMS policy requires Contractors/Subcontractors receive security training commensurate with their responsibilities for performing work under the terms and conditions of their contractual agreements. The DVC shall retain the results of security awareness and role-based information security technical training. CMS requires basic security awareness training for employees and contractors that support the operation of the DVC systems. CMS requires information security technical training to information system security roles. Training shall be consistent with the requirements contained in C.F.R. Part 5 Subpart C (5 C.F.R. 930.301) and conducted at least annually.

Privacy Documentation

The DVC shall be responsible for coordinating with the CMS Privacy Office (<http://www.cms.gov/PrivacyOffice/>) in preparing and maintaining current all documentation including but not limited to System of Records Notification (SORN) and Privacy Impact Assessments (PIA) which directly and indirectly relating to its program(s) designed to ensure the confidentiality, integrity, and

The Centers for Medicare & Medicaid Services
 RAC Data Validation Contractor SOW – Division of Plan Oversight and Accountability

availability of Federal Information and Federal Information System, and its assets that enable its possession or control.

System Authorization and Assessment

The implementation of a Federal Government IT system requires a formal Government Authorization to Operate (ATO), formerly certification and accreditation, of infrastructure systems and/or all application systems developed, hosted and/or maintained on behalf of CMS. NIST Special Publication 800-37, (hereafter described as NIST 800-37) and CMS procedures (located on the CMS Information Security “Virtual Handbook” Web site at: <http://www.cms.gov/InformationSecurity>) give guidelines for performing the system ATO process. The system/application must have a valid ATO (conveyed through the CMS CIO authorization decision process) before going into operation and processing CMS information. The failure to obtain and maintain a valid ATO may be grounds for termination of the contract.

- 1) The DVC shall comply with Authorization to Operate (ATO) requirements as mandated by Federal laws and policies, including making available any documentation, physical access, and logical access needed to support this requirement. The Level of Effort for the ATO is based on the System’s NIST Federal Information Processing Standard (FIPS) Publication 199 categorization and CMS procedures (located on the CMS Information Security “Virtual Handbook” Web site at <http://www.cms.gov/InformationSecurity>). The contractor shall coordinate with the CMS business owner to create, maintain and update all applicable ATO documentation as defined by CMS Information Security procedures.
- 2) At the Moderate and High impact levels, all CMS systems and infrastructures must obtain an independent Security Assessment in accordance with CMS procedures (located on the CMS Information Security “Virtual Handbook” Web site at: <http://www.cms.gov/InformationSecurity>). The Contractor shall allow CMS employees (or CMS designated third-party contractors) to conduct Security Assessment activities to include control reviews in accordance with NIST 800-53/NIST 800-53A and CMS procedures (located on the CMS Information Security “Virtual Handbook” Web site at: <http://www.cms.gov/InformationSecurity>). This includes the general support system infrastructure.
- 3) Identified gaps between required controls and the DVC’s implementation as documented in the Security Assessment report shall be tracked for mitigation in a Plan of Action and Milestones (POA&M) document completed in accordance with CMS procedures (located on the CMS Information Security “Virtual Handbook” Web site at: <http://www.cms.gov/InformationSecurity>). Depending on the severity of the gaps, the Government may require them to be remediated before an Authorization to Operate is issued.
- 4) The DVC shall be responsible for mitigating all applicable security risks found during the ATO process and continuous monitoring activities. All high-risk vulnerabilities must be mitigated within 30 days and all moderate risk vulnerabilities must be mitigated within 90 days from the date vulnerabilities are formally identified. The Government will determine the risk rating of vulnerabilities.

Continuous Monitoring

CMS has the right to perform manual or automated audits, scans, reviews, or other inspections of the Contractor’s IT environment being used to provide or facilitate services for CMS in support of the Federal requirements to perform continuous monitoring

The Centers for Medicare & Medicaid Services
 RAC Data Validation Contractor SOW – Division of Plan Oversight and Accountability

Automated scans can be performed by Government personnel, or agents acting on behalf of the Government, using Government operated equipment, and Government specified tools.

CMS established a centralized Security Operations Center (SOC) to provide a robust enterprise continuous monitoring program to improve situational awareness and provide near real-time risk management. The SOC provides information security oversight and monitoring of security events across all information systems that support the operations and assets of CMS, and will notify the appropriate security operations staff of potentially malicious traffic.

In addition to the requirements to meet all of the CMS Information Security requirements documented in the <http://www.cms.gov/InformationSecurity> Web site, the DVC shall work closely with the SOC to undertake security related activities including but not limited to the following

- 1) Contractor shall be responsible for supporting the CMS continuous monitoring program by providing automated data feeds to the SOC as required by the CMS CISO. The SOC will supplement this by conducting independent oversight continuous monitoring activities such as, but not limited to, vulnerability and compliance scanning as well as other network monitoring related activities of all the CMS information systems.
- 2) Contractor shall provide updated network architecture, IP address ranges, and security points of contact information for the systems they operate on behalf of CMS to the SOC on a quarterly basis (Jan 1, April 1, July 1, and Oct 1).
- 3) Contractor shall maintain and provide changes to the system accounts needed for the SOC credentialed scanning two weeks before the passwords expire or when other changes to the accounts are needed.
- 4) Contractor shall provide rack space, cabling, connectivity, and appropriate environmental support for SOC-managed systems/appliances as required by the CMS CISO.

Federal Desktop Core Configuration (as applicable)

The DVC shall certify applications are fully functional and operate correctly as intended on systems using the Federal Desktop Core Configuration (FDCC). This includes Internet Explorer configured to operate on Windows. The standard installation, operation, maintenance, updates, and/or patching of software shall not alter the configuration settings from the approved FDCC configuration. The information technology should also use the Windows Installer Service for installation to the default "program files" directory and should be able to silently install and uninstall. Applications designed for normal end users shall run in the standard user context without elevated system administration privileges. The DVC shall use Security Content Automation Protocol (SCAP) validated tools with FDCC Scanner capability to certify their products operate correctly with FDCC configurations and do not alter FDCC settings. Deviations must be approved by the CMS CISO.

The DVC shall monitor and adhere to all IT policies, standards, procedures, directives, templates, and guidelines that govern the CMS IS Program, <http://www.cms.hhs.gov/informationsecurity>. Some applicable references are provided below:

- *CMS Policy for Information Security* (As amended) – The high level CMS policy for the CMS Information Security Program
- *CMS Policy for the Information Security Program (PISP)* (As amended) - Sets the ground rules under which CMS shall operate and safeguard its information and information systems to reduce the risk and minimize the effect of security incidents. This document will subsequently reference Contractors/Subcontractors applicable CMS security Standards and procedure

The Centers for Medicare & Medicaid Services
 RAC Data Validation Contractor SOW – Division of Plan Oversight and Accountability

- *CMS Policy for Investment Management and Governance* (As amended) - Establishes the policy for systematic review, selection/reselection, implementation/control, and continual evaluation of IT investments at CMS.

Section 508

This SOW is subject to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) as amended by the workforce Investment Act of 1998 (P.L. 105-220). Specifically, subsection 508 (a)(1) requires that when the Federal Government procures Electronic and Information Technology (EIT), the EIT must allow Federal employees and individuals of the public with disabilities comparable access to and use of information and data that is provided to Federal employees and individuals of the public without disabilities.

The EIT accessibility standards at 36 CFR Part 1194 were developed by the Architectural and Transportation Barriers Compliance Board ("Access Board") and apply to contracts and task/delivery orders, awarded under indefinite quantity contracts on or after June 25, 2001.

Each Electronic and Information Technology (EIT) product or service furnished under this contract shall comply with the Electronic and Information Technology Accessibility Standards (36 CFR 1194), as specified in the contract, as a minimum. If the Contracting Officer determines any furnished product or service is not in compliance with the contract, the Contracting Officer will promptly inform the Contractor in writing. The Contractor shall, without charge to the Government, repair or replace the non-compliant products or services within the period of time to be specified by the Government in writing. If such repair or replacement is not completed within the time specified, the Government shall have the following recourses:

1. Cancellation of the contract, delivery or task order, purchase or line item without termination liabilities; or
2. In the case of custom Electronic and Information Technology (EIT) being developed by a contractor for the Government, the Government shall have the right to have any necessary changes made or repairs performed by itself or by another firm for the noncompliant EIT, with the contractor liable for reimbursement to the Government for any expenses incurred thereby.

The DVC must ensure that all EIT products that are less than fully compliant with the accessibility standards are provided pursuant to extensive market research and are the most current compliant products or services available to satisfy the contract requirements.

As discussed in the sections above, the RAC is required to complete the IPRP, No Determination Report, IPRP Validation Findings dispute, and the Notification of Improper Payment Letters, as applicable for each audit issue/contract.

5.0 Key Personnel/Other Personnel

The DVC shall maintain a staff of key personnel positions as necessary and within the requirements identified below. Key personnel shall not serve dual responsibilities in key functions unless approved by the Contracting Officer, i.e., the Program Director may not also serve as the Audit Manager. Changes in

The Centers for Medicare & Medicaid Services
RAC Data Validation Contractor SOW – Division of Plan Oversight and Accountability

key personnel positions shall be submitted to the Contracting Officer in writing for approval within 30 days prior to any change.

A significant amount of confidential information will be reviewed under this contract. Therefore, all contractor and subcontractor personnel working on this SOW shall submit a signed Non-Disclosure Statement.

When key personnel positions are vacated due to unforeseen circumstances, a proposed replacement shall be submitted in writing for approval no later than 30 calendar days from the date the position was vacated. Interim replacements should be identified when a permanent replacement cannot be identified within this time frame. CMS may consider a 60-day interim replacement until a permanent replacement is secured.

Unless otherwise approved by the Contracting Officer, the key personnel noted below shall possess the following minimum work experience and educational requirements:

Program Manager

The Program Manager shall possess:

Work Experience

Ten or more years of professional experience with at least three years as a manager responsible for managing complex systems and work flow. Experience in audit recoveries is required.

Educational Requirements

A bachelor's degree from an accredited institution, plus a master's degree from an accredited institution or substitution of 4 additional years of related work experience in lieu of the master's degree

Audit Manager – Examinations (AME)

The Audit Manager shall possess:

Work Experience

A minimum of 5 years in an audit and reimbursement setting. Medicare audit and reimbursement setting is preferred.

Understanding of Government Auditing Standards, audit procedures, and financial analysis techniques.

Educational Requirements

An advanced degree in finance or accounting. Certified Public Accountant (CPA) or Certified Management Accountant (CMA) certificate is desired.

Audit Manager – Reimbursement (AMR)

The Audit Manager shall possess:

Work Experience

A minimum of 5 years in an audit and reimbursement setting. Medicare audit and reimbursement setting is preferred.

The Centers for Medicare & Medicaid Services
RAC Data Validation Contractor SOW – Division of Plan Oversight and Accountability

Understanding of Government Auditing Standards, audit procedures, and financial analysis techniques

Educational Requirements

An advanced degree in finance or accounting; Certified Public Accountant (CPA) or Certified Management Accountant (CMA) certificate is desired.

Systems Security Officer

The Systems Security Officer shall possess:

Work Experience

A minimum of 5 years of experience managing complex security programs/systems, implementing necessary safeguards, and ensuring all artifacts are current and up-to-date.

Educational Requirements

A bachelor's and a master's degree; 5 additional years of related work experience may be substituted in lieu of master's degree.

Lead Statistician

The Lead Statistician shall possess the following:

Work Experience

A minimum of 5 years experience using statistics to support corporate/business information needs.

Experience in statistical detection of fraud, fuzzy logic, development of mathematical models, neural networks, and data mining or other analytical methods. Demonstrated experience and knowledge of health care information (health claims data, provider identifiers, etc)

Educational Requirements

Bachelor's degree in statistics or related field.

Other Personnel

Although not considered key personnel positions, the following labor category personnel may be required for this SOW. When required, the respective job classification requirements are essential for performance under this contract. Waiver(s) from the essential personnel requirements may be submitted in writing to the Contracting Officer for approval. All waiver requests should include a copy of a resume along with supporting rationale for the deviation from these requirements

Data Analyst

The Data Analyst shall possess the following:

Work Experience

A minimum of 3 years of experience using various data sources to support corporate/business information needs.

The Centers for Medicare & Medicaid Services
 RAC Data Validation Contractor SOW – Division of Plan Oversight and Accountability

Experience in managing, analyzing, interpreting and transforming data in the detection of fraud, waste, and abuse. Demonstrated experience and knowledge of health care information (health claims data, provider identifiers, etc.)

Educational Requirements

Bachelor's degree in business administration, statistics, information technology or related field.

Pharmacist

The Pharmacist shall possess the following:

Work Experience

A minimum of 5 years experience in prescription drug benefit management with three 3 years experience managing a prescription drug formulary, medication therapy management, and drug interaction program

The Pharmacist shall have experience in the development of plans and the review of claims to ensure clinically appropriate utilization. This shall include experience in claims analysis, claims data review for abnormalities, auditing of claims, and setting up edits and audits to ensure proper utilization of benefits. The Pharmacist shall also have knowledge and experience concerning the current uses of medications, new or emerging issues, issues related to electronic prescribing, among other general knowledge and experience in the prescription drug benefits. A minimum of 1-2 years experience working in a retail pharmacy as a licensed pharmacist is strongly preferred.

Educational Requirements

The Pharmacist shall be a board trained certified pharmacist with a Doctorate of Pharmacy (Pharm.D) and trained in Biochemistry, Chemistry and Pharmacokinetics.

6.0 Quality Assurance

CMS will utilize a number of quality assurance procedures to ensure contractor compliance with this SOW. Examples include inspection of deliverables, review of reports, onsite progress meetings, performance evaluations, etc.

The DVC shall develop and maintain quality assurance procedures for work paper reviews, IT requirements, etc. The DVC shall also ensure that data is physically secured and Personal Health Information (PHI) data is handled confidentially. This is required for subcontractors as well. These should be provided to CMS upon request.

6.1 DVC Oversight

CMS will conduct DVC oversight at either the DVC's site or at the appropriate CMS office. CMS has the right to request/review any work performed by the contractor at any time; this includes work papers, reports, support for findings, etc. After completion of the engagement, CMS may hold a conference with the DVC to discuss any issues. CMS may choose to visit the DVC site to assess their performance.

The Centers for Medicare & Medicaid Services
 RAC Data Validation Contractor SOW – Division of Plan Oversight and Accountability

6.2 Cooperation/Coordination

The DVC shall cooperate and coordinate with stakeholders other than CMS, including Affiliated Contractors (ACs), and other entities as appropriate. Contractor performance will be evaluated using measures including, but not limited to:

- Demonstration of ongoing dialogue or meetings with the appropriate and necessary parties;
- Feedback from other entities; and
- Number and type of issues that arise and indicate communication, or lack of communication, between appropriate entities and the Contractor.

6.3 Quality

The DVC shall maintain the highest degree of quality for all activities performed throughout the period of performance of the contract. CMS will evaluate the DVC performance using measures including, but not limited to:

- Completeness and accuracy of data analysis;
- Completeness and accuracy of all deliverables

6.4 Standard Operating Procedures

The DVC shall follow the procedures that are outlined in the SOPs submitted by CMS/CPI.

6.5 CMS Systems

The DVC shall maintain CMS system access to review Medicare Part D Data and to store and track Medicare Part D improper payments.

Government Property:

Government property has been issued on this contract, which CMS granted Permission for Livanta to use property from the MEDIC RDS Task Order. Livanta currently submits inventory requests to the CMS property administrator with a copy to the Contracting Officer in October of each year.

7.0 Transitions

From time to time in the DVC program transitions from one DVC to another DVC will need to occur. It is in the best interest of all parties that these transitions occur smoothly.

The transition plan will include specific dates with regard to any outstanding reports for new issue reviews, accuracy reviews, and special studies. The transition plan will be communicated to all affected parties (including subcontractors) by CMS within 60 days of its enactment.

The Centers for Medicare & Medicaid Services
RAC Data Validation Contractor SOW – Division of Plan Oversight and Accountability

The Centers for Medicare & Medicaid Services
 RAC Data Validation Contractor SOW – Division of Plan Oversight and Accountability

APPENDIX B - ITEMS TO BE FURNISHED AND DELIVERABLE SCHEDULE

The DVC shall submit all required reports and deliverables in accordance with the statement of work and the following schedule.

ITEM NO.	SECTION NO.	DESCRIPTION	RECIPIENT	DELIVERY
1	2.1.1	New Issue Review Report	COR	25 days after receipt of claims
2	2.2.1	Validation Findings Report	COR	45 days after receipt of claims
3	2.2.1	Cumulative Accuracy Rate Report	COR	Annually Draft due 30 days after the end of fiscal year. Final due 30 days following draft deliverable to CMS
4	2.3.1	Dispute Form	COR	7 days after receipt of form
5	3.0	Special Studies Report	COR	As needed
6	4.1	System Security Plan	COR	14 days after contract award
7	4.1	Project Work Plan	COR	14 days after contract award
8	4.1	Quality Assurance Plan	COR	30 days after contract award; updated as needed
9	4.1	Monthly Progress Report	COR	10th day of the month for the previous month's effort
10	4.1	DVC Operations Manual	COR	30 days after contract award; quarterly thereafter
11	4.1	Vulnerability Tracking	COR	Monthly
12	4.1	Conference Calls	COR	Biweekly/As needed

The Centers for Medicare & Medicaid Services
RAC Data Validation Contractor SOW – Division of Plan Oversight and Accountability

APPENDIX C – CMS Contacts

Contracting Officer

Nicole Hoey
410-786-0489
7500 Security Boulevard
Baltimore, MD 21244
Nicole.Hoey@cms.hhs.gov

Contracting Specialist

Justin Menefee
410-786-7629
7500 Security Boulevard
Baltimore, MD 21244
Justin.Menefee@cms.hhs.gov

Contracting Officer's Representative

India Thomas
410-786-1152
7500 Security Boulevard
Baltimore, MD 21244
India.Thomas@cms.hhs.gov